REMARKS

Claims 1 and 49-72 are pending in this application.

Applicants respectfully request reconsideration and withdrawal of the rejections in view of the arguments set forth below.

Rejection of Claims 1, 49-70 Under 35 U.S.C. § 102(b) in view of Gerstel et al. (U.S. Pat. No. 3,964,482, or "Gerstel")

Claims 1 and 49-70 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gerstel. The Office Action argues, *inter alia*, that Gerstel discloses in col. 10-11 that "the substrate (14) and/or the microneedle being formed from flexible material." The Office Action further argues that Applicants' arguments advanced in the last Office Action response are rendered moot by this new ground of rejection.

Applicants respectfully traverse this rejection, because the Office Action does not explicitly point out or explain, and Applicants are unable to find where in col. 10-11 of Gerstel is the disclosure that the substrate **14** and/or the microneedle being formed from flexible materials. Clarification is respectfully requested.

Although Applicants disagree, the only disclosure in col. 10-11 that *may* be close to such disclosure is in the paragraph bridging columns 10 and 11, and the few paragraphs thereafter, where Gerstel describes that "projections **12**, base **24**, ... can be formed of a drug release rate controlling material." Gerstel then describes a huge list of possible materials that can be such drug release rate controlling materials, none of which is taught by Gerstel or asserted by the Examiner as being flexible.

As Gerstel describes in the paragraph bridging paragraphs 11 and 12, the key quality that makes a material a good candidate for drug release rate control is "its structure, its degree of saturation, the presence of cross-linking, the solubility of the drug in the material, the thickness of the material..." There is no mentioning anywhere of flexibility being a relevant factor.

In fact, Gerstel explicitly *teaches away* from the feature of flexibility in col. 8, lines 30-42, by characterizing the suitable materials for base **24** as having "high degree of impact

strength," "good hardness," "resistance to deformation," "good tensile strength," *etc.*, such as "metals and alloys," "steels," *etc.*:

> "The puncturing projections **12** and base **24**, as described above, can be made from a wide variety of materials. One class of suitable materials is polymers and the polymeric derivatives thereof. The polymers acceptable for forming puncturing projections of solid design (which carry drug along their exterior surface) or projections made with a passageway and openings at both ends are materials characterized by properties such as a high degree of impact strength, good hardness, resistance to deformation, good tensile strength, does not adversely effect the drug or the host, and readily lend themselves to forming puncturing projections for penetrating or piercing the stratum corneum.
> ...
> Puncturing projections **12** and base **24** of this design can also be made from other materials such as metals and alloys. Examples of metals and alloys include stainless steel; tungsten steel; manganese steel; tantalum; titanium alloys consisting of nickel, molybdenum and chromium; vitallium alloys consisting of cobalt, chromium and molybdenum; and the like."
>
> (emphasis added)

Even assuming, for the sake of argument, that *some* materials in the long list of drug release rate controlling materials happen to be flexible, Gerstel still cannot anticipate the pending claims for at least two reasons.

First of all, even if *some parts* of the Gerstel devices (see Figures 1-6 of Gerstel) may be made of a drug release rate controlling material that happens to be flexible, it does not necessarily mean that the device itself is flexible so as to "allow the device to fit the contour of the biological barrier," as recited in the claims. For example, in Figure 5 of Gerstel, membrane **34** is formed of a drug release rate controlling material, while base membrane **24** and puncturing projections **12** can be formed "from a single piece of stainless steel..." It is difficult to imaging that the device in Figure 5 can fit the contour of the biological barrier given its steel construction at the bottom.

Secondly, this rejection is in essence the same as the previous rejection, where the Office Action rejects the claimed invention on the basis that the broadly disclosed genus of "thermoplastic materials" allegedly anticipates the claimed species of "flexible material." Here, the Office Action rejects the claimed invention on the basis that the broadly disclosed genus of "drug release rate controlling material" allegedly anticipates the species of "flexible material." Applicants respectfully disagree for the same reason in record.

To reiterate, there is no doubt that a species will anticipate a claim to a genus. *In re*

Slayter, 276 F.2d 408, 411 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989). Also *see* MPEP 2131.02. However, the reverse is generally not true, *i.e.*, a broadly disclosed genus generally does not anticipate a species within the genus, unless: (1) such a species is "clearly named," or (2) "when the species can be 'at once envisaged' from the (genus) formula." MPEP 2131.02.

As argued above, Gerstel does not "clearly name" the recited "flexible material." The Office Action fails to specifically point out where in Gerstel (especially in col. 10-11) such "flexible material" is disclosed. Neither can Applicants identify such a disclosure in Gerstel.

Applicants also submit that a skilled artisan cannot "at once envisage" the recited flexible material from the broad Gerstel disclosure of "drug release rate controlling materials." Applicants wish to draw the Examiner's attention to the controlling case law *Akzo N.V. v. International Trade Comm'n*, 808 F.2d 1471 (Fed. Cir. 1986).

In *Akzo*, claims to a process for making aramid fibers using a 98% solution of sulfuric acid were found not anticipated by a cited reference, which disclosed using sulfuric acid solution, but which did not disclose using a 98% concentrated sulfuric acid solution. The Federal Circuit, after reviewing the International Trade Commission (ITC) investigation record, held that the factual findings of the Administrative Law Judge (ALJ) presiding over the investigation were supported by substantial evidence. Thus the court affirmed the ALJ conclusion that "sulfuric acid in any concentration was not disclosed as a solvent in the reference." *Akzo*, 808 F.2d at 1480. The court also found that the ALJ properly relied on *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) to reject "random picking and choosing" of prior art, and affirmed the ALJ conclusion that "the anticipatory reference must disclose in the prior art a thing substantially identical with the claimed invention. In a somewhat more limited consideration - restricted to the concentration of sulfuric acid in the Blades patent" (emphasis added). *Akzo*, 808 F.2d at 1480.

If "sulfuric acid solution" does not anticipate the claimed "98% concentrated sulfuric acid solution," Applicants submit that "drug release controlling materials" cannot anticipate "flexible (drug release controlling) materials." Gerstel explicitly teaches that the base **24** "can be made from a wide variety of materials," including such non-flexible and "resisting to deformation" materials as metal, alloy, and steel. Therefore, a skilled artisan could not imagine, let alone "at once envisage" from this broad genus any specific species, especially those species materials that are flexible.

Therefore, Applicants submit that Gerstel does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) are respectfully requested.

Claim Rejections under 35 U.S.C. § 103(a)

Claim 72 is rejected under 35 U.S.C. § 103(a) as allegedly obvious over Gerstel as modified by Eicher *et al.*, or by Godshall *et al.*

As discussed above, Applicants reiterate that the pending claims recite features neither disclosed nor suggested by Gerstel. Neither Eicher nor Godshall teach or suggest the subject matter recited in the amended independent Claim 70, from which Claim 72 depends. Thus Claim 72 is patentable for the same reasons that Claims 1 and 70 are patentable. Thus, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

We believe that we have appropriately provided for fees due in connection with this submission. However, if there are any other fees due in connection with the filing of this Response, please charge the fees to our Deposit Account No. **18-1945**, from which the undersigned is authorized to draw under the Order No. **BVTP-P04-506**.

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Respectfully submitted,

By _____ Reg. No. 55,745

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